Clinical Coverage Policy No. 11G Original Date: January 1, 1994 Revised Date: December 1, 2005

1.0 Definition of the the Procedure

Photopheresis (extracorporeal) for the treatment of solid organ rejection and photopheresis as treatment for autoimmune disease vs. host disease involves the reinfusion of autologous photosensitized blood. The blood is photosensitized with drugs and ultraviolet A light prior to being infused back into the recipients body. This procedure is used in persons with Graft Versus Host Disease (GVHD), a condition that occurs when the a donor's immune cells in bone marrow make antibodies against the host's (transplant recipient) tissues and attack the patient's vital organs.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

3.0 When the Procedure is Covered

The N.C. Medicaid program covers photopheresis for the treatment of chronic GVHD that is refractory to adequate test of medical therapy.

Note: Must provide documentation of failed responses to medical therapies.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

4.0 When the Procedure is Not Covered

The N.C. Medicaid program does not cover photopheresis for the treatment of solid organ rejection and autoimmune disease vs. host disease for the conditions:

- 1. extracorporeal photopheresis for the treatment of all solid organ transplant rejection
- 2. acute GVHD

CPT codes, descriptors, and other data only are copyright 2004 American Medical Association. All rights reserved. Applicable FARS/DFARS apply.

- 3. chronic GVHD that is previously untreated or responding to conventional medical therapies
- 4. other conditions, including but not limited to autoimmune diseases, i.e. systemic lupus erythematous, scleroderma, rheumatoid arthritis, pemphigus, psoriasis, diabetes, multiple sclerosis, etc.

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- 5. history of active substance abuse must have documentation of substance abuse program completion plus six months of negative sequential random drug screens
 - **Note:** To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
- 6. Psychosocial history that would limit the ability to comply with medical care pre and post transplant.
- 7. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by DMA.

If prior approval has been given for stem cell transplants, donor expenses (**procuring**, **harvesting**, **short-term storing and all associated laboratory costs**) are covered.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of the procedure.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

Division of Medical Assistance
Photopheresis For Solid Organ Rejection,
Autoimmune Disease and GVHD

Clinical Coverage Policy No. 11G Original Date: January 1, 1994 Revised Date: December 1, 2005

Policy Implementation/Revision Information Original Effective Date: January 1, 1994 8.0

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective
		with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions
		was added to this section.

Division of Medical Assistance Photopheresis For Solid Organ Rejection, Autoimmune Disease and GVHD

Attachment A Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

- 1. Providers bill professional services on the CMS-1500 claim form.
- 2. Donor expenses are billed on the recipient claim.
- 3. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

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C. Procedure Codes

Codes that are covered include: 36522

D. Providers must bill their usual and customary charges.